REMARKS

In response to the Office Action of January 28, 2009, the present application has been carefully reviewed and amended. Entry of the present amendment and reconsideration of the application are respectfully requested.

In the outstanding Office Action, the scope of at least Claims 1 and 16 were deemed to have been changed to a non-elected invention, and thus non-responsive. [Paper 20090128, page 1].

The Examiner cites the disclosure of [0065] as supporting the originally filed claims. That is, the "method involves employing an indicator that dilutes the density of the blood passing though the tubing (see paragraph 0065), as was originally set forth in the claims of the application." [Paper 20090128, page 1].

Paragraphs [0065 and 00066] of the application as filed (paragraphs [0070 and 0071] as published), provide:

> **[0070]** Another method of calibrating the sensitivity of the probe is to employ an indicator which dilutes the photometric density of the blood passing through the tubing **50**. For example, an injection of an indicator, such as normal saline or another conventional solution, is made into an injection port of the dialysis system. The indicator injection should be made upstream from the probe **10**, so that all the indicator passes through the probe between the light port **22** and the photodetector **40**. The indicator injection causes the optical property of the blood to change, thus changing the light intersecting the photodetector **40** along the detection vector. The change in the amount of detected scattered light is registered by the probe **10**, and specifically the photodetector **40**. Coefficient K can then be calculated through the volumes:
>
> $$K = -\frac{V_{Inj}}{V + V_{Inj}} * \Delta U_{Inj}$$ (Equation 8)
>
> **[0071]** where V_{inj} is injection's volume; $V=(Q_B-Q_{UF})*\Delta T_{inj}$, ΔT_{inj} is the transit time of the injection bolus; and ΔU_{inj} is integrated over ΔT_{inj} registered signal change.

That is, paragraph [0065 (0070)] provides for calibration of the blood corresponding to an ultrafiltration rate Q_{UF}.

Amended Claim 1 recites in part "providing an ultrafiltration rate in the dialysis system ... determining a calibration coefficient of the blood property sensor corresponding to the determined blood property of the filtered blood and the ultrafiltration rate."

Amended Claim 16 recites in part "(a) providing one of an ultrafiltration rate and a change in an ultrafiltration rate in a dialyzer in the extracorporeal blood circuit ... determining a calibration coefficient of the blood property

sensor corresponding to the measured blood property and the one of the an ultrafiltration rate and a change in an ultrafiltration rate."

Applicant notes the restriction in the parent application (08/950,244) was not between (i) calibrating a blood property sensor corresponding to a bolus injection and (ii) calibrating a blood property sensor corresponding to a change in an ultrafiltration rate, but rather:

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

   I. Claims 1 - 9 and 15 - 24, drawn to a method for determining blood parameters including detecting the light at an angle to substantially eliminating light scattering in the blood, classified in class 600, subclass 322.

   II. Claims 10 - 14, drawn to a method for calibrating a blood property optical sensor, classified in class 600, subclass 322.

   III. Claims 25 - 32, drawn to an apparatus for measuring blood parameters in conjunction with injection with an indicator bolus, classified in class 600, subclass 322.

   IV. Claims 33 and 34, drawn to a method of passive extracorporeal connection, classified in class 604, subclass 19.

Therefore, applicant respectfully submits the present claims involve the subject matter employed in the claims originally filed in the present application, and not improperly shifted subject matter as between previously restricted inventions.

As set forth in the amendment filed December 19, 2008 to the Office Action of August 19, 2008, the application was carefully reviewed and amended.

Claim Objections

Claims 1-11, and specifically Claims 1, 8 and 9, are objected to various reasons as set forth on Page 2, paragraph 1 of the Office Action mailed August 19, 2008.

Each of these claims[1] was amended to overcome the objections.

Claim Rejection under 35 USC §112

Claim 3 was rejected under 35 USC §112 second paragraph.

Claim 3 has been cancelled, and thus this rejection was believed overcome.

Claim Rejection under 35 USC §102

Claims 8-18 stood rejected under 35 USC §102 as being anticipated by Krivitski (US Patent 5,453,576) [Paper 20080812, page 3]

[1] Claim 3 has been cancelled.

As cited by the Examiner, the calibration of Krivitski '576 is:

> Another way to calibrate the perivascular sensors or the clamp-on tube sensors of FIGS. **10** and **11** is to make a calibration injection of a known indicator material directly prior to the location of the sound velocity sensor while simultaneously measuring the blood flow through the tube/vessel. A calibration injection into the arterial line, for example by way of arterial inlet ports **230** or **232** in the systems of FIGS. **10** and **11**, respectively, will change the measured sound velocity in the arterial sensors **112** or **180** as follows:
>
> $$\Delta C(t)=\Delta C_b(t)*l_b/(l_t+l_b) \quad \text{(Eq. 12)}$$
>
> or
>
> $$S_{A.cal.isol.sound}=S_{A.b.cal.isol.sound.}*l_b/(l_t+l_b) \quad \text{(Eq. 13)}$$
>
> where $S_{A.cal.isol.sound.}$ is the measured sound velocity dilution area generated by blood sound velocity dilution changes ($S_{A.b.cal.isol.sound}$). From equations 6 and 13 the average flow through the tube/vessel during the time when the indicator passes is expressed as follows:
>
> $$Q_{A.cal.}=\frac{(A_1P+2A_2P_2)\dot{V}_{A.cal.isol.}*l_b}{S_{A.cal.isol.sound}(l_t+l_b)} \quad \text{(Eq. 14)}$$
>
> where $Q_{A.cal.}$ is the average flow through the tube/vessel and $V_{A.cal.isol.}$ is the volume of the calibrating injection. (Col. 11)

That is, Krivitski '576 employs a calibration injection into the arterial line and the measurement of sound velocity in arterial sensors (based on l_t and l_b, where l_t is the equivalent path length of ultrasound in the tube/vessel and l_b is the equivalent path length through the blood). [Krivitski '576, Col. 10, lines 7-10]

Claims 8-11

Claims 8-11 were amended to recite in part "determining a calibration coefficient of the blood property sensor corresponding to the measured

property of the diluted blood and an ultrafiltration rate of a dialyzer in the extracorporeal portion."

There is no disclosure in Krivitski '576 of determining a calibration coefficient of the blood property sensor in the extracorporeal portion corresponding to the measured property of the diluted blood and an ultrafiltration rate of a dialyzer in the extracorporeal portion.

As at least this limitation is absent from Krivitski '576, the outstanding rejection of Claims 8-11 has been overcome.

Claims 12-14

Claims 12-14 were amended to recite in part "means for determining a calibration coefficient of the blood property sensor corresponding to the detected property of the diluted blood and one of an ultrafiltration rate and a change in the ultrafiltration rate of a dialysis system in the extracorporeal portion."

Krivitski '576 employs a calibration injection into the arterial line and the measurement of sound velocity in an arterial sensor (based on l_t and l_b, where l_t is the equivalent path length of ultrasound in the tube/vessel and l_b is the equivalent path length through the blood). [Krivitski '576, Col. 10, lines 7-10].

Therefore, as the presently recited "change in the ultrafiltration rate of a dialysis system in the extracorporeal portion" is not disclosed in Krivitski '576, Claims 12-14 are in condition for allowance.

Claim 15

Claim 15 was amended to recite in part "means connected to the blood property sensor for determining a calibration coefficient of the blood property sensor corresponding to the detected property of the diluted blood in the extracorporeal portion and one of an ultrafiltration rate and a change in the ultrafiltration rate of a dialysis system in the extracorporeal portion."

Krivitski '576 does not disclose the determination of a calibration coefficient corresponding to one of an ultrafiltration rate and a change in the ultrafiltration rate of a dialysis system in the extracorporeal portion. Therefore, Claim 15 is in condition for allowance.

Claim 16

Independent Claim 16 has now been amended to recite in part (a) providing one of an ultrafiltration rate and a change in an ultrafiltration rate in a dialyzer in the extracorporeal blood circuit; (b) measuring a blood property at a blood property sensor in the extracorporeal blood circuit; and (c) determining a calibration coefficient of the blood property sensor corresponding to the measured blood property and the one of the an ultrafiltration rate and a change in an ultrafiltration rate."

Krivitski '576 does not disclose determining a calibration coefficient corresponding to an ultrafiltration rate in a dialyzer. Therefore, Claim 16 is in condition for allowance.

Claim 17

Claim 17 was amended to recite in part "determining a calibration coefficient of the blood property sensor corresponding to the measured change and an ultrafiltration rate of a dialyzer in the extracorporeal blood circuit."

The use of a calibration injection [Krivitski '576, Col. 11, line 15] does provide for the presently recited determination corresponding to an ultrafiltration rate of dialyzer in the extracorporeal blood circuit. Therefore, Claim 17 is in condition for allowance.

Claim 18

As previously amended, Claim 18 recites in part "determining the calibration coefficient of the blood property sensor corresponding to the measured blood property and one of an ultrafiltration rate and a change in the ultrafiltration rate of a dialysis system in the extracorporeal blood circuit."

The use of a calibration injection [Krivitski '576, Col. 11, line 15] does provide for the presently recited determination corresponding to one of an ultrafiltration rate and a change in the ultrafiltration rate of a dialysis system in the extracorporeal blood circuit. Therefore, Claim 18 is in condition for allowance.

Claim Rejections under 35 USC §103

Claims 1-7 stood rejected under 35 USC §103 as being unpatentable over Krivitski (US Patent 5,453,576) [Paper 20080812, page 3]

Claims 1-7 have been amended to recite in part "(a) connecting an arterial tubing portion of a dialysis system to withdraw blood from a patient and connecting a venous tubing portion of the dialysis system to deliver filtered blood to the patient; (b) providing an ultrafiltration rate in the dialysis system; (c) determining at least one property of the filtered blood passing a blood property sensor in the venous tubing portion; and (d) determining a calibration coefficient of the blood property sensor corresponding to the determined blood property of the filtered blood and the ultrafiltration rate."

Krivitski '576 does not disclose providing an ultrafiltration rate in the dialysis system or "determining a calibration coefficient of the blood property sensor corresponding to the determined blood property of the filtered blood and the ultrafiltration rate." The absence of at least these limitations overcomes the outstanding rejection.

Further, Krivitski '576 does not disclose that the sensors in the venous portion can be calibrated in the same manner as the sensors in the arterial portion.

With respect to the equivalence of the arterial and the venous sensors, applicant respectfully submits there is no reasonable expectation that the same calibration technique of Krivitski '576 would apply in the venous portion. That is, the dialysis system of Claims 1-7 changes the blood to filtered blood, thus the filtered blood has different characteristics than the (unfiltered) blood. There is no reason to expect that filtered blood would provide an basis for

determining a calibration coefficient in a blood property sensor in the venous tubing portion (downstream of the dialysis system). In fact, the filtered blood, being different from the blood in the arterial line suggests that the blood property sensor in the venous tubing portion cannot be calibrated as a blood property sensor in the arterial tubing portion.

The absence of at least these two limitations overcomes the outstanding rejection of Claims 1-7 under 35 USC §103.

Therefore, applicant respectfully submits all the pending claims, Claims 1, 2 and 4-18 are in condition for allowance, and such action is earnestly solicited. If, however, the Examiner believes that any further issues remain, the Examiner is cordially invited to call the undersigned so that any such matters can be promptly resolved.

Please grant any extensions of time required to enter this response and charge any required fees to our deposit account 033875.

Respectfully submitted,

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/Brian Shaw/

Brian B. Shaw, Registration No. 33,782
Harter Secrest & Emery LLP
1600 Bausch & Lomb Place
Rochester, New York 14604
Telephone: 585-232-6500
Fax: 585-232-2152